Annual Report of the Scrutiny Committee 2021

1. Introduction

As Chair of the Scrutiny Committee, I have compiled the ninth Annual Report of the Committee's work in compliance with Regulation 7(1) of the Council of the Pharmaceutical Society of Northern Ireland (Statutory Committee, Scrutiny Committee and Advisers) Regulations (Northern Ireland) 2012 for the year 01 January 2021 to 31 December 2021.

1.1 The legislation states as follows at Regulation 7(1):

7(1) The Scrutiny Committee has the following additional functions—

(a) providing an annual report to the Council in respect of each calendar year, by a date specified by the Council, which is to include

(i) trends, patterns and learning points observed from cases considered by the Scrutiny Committee,
(ii) details of the numbers of fitness to practise and disqualification allegations which were disposed of by the Scrutiny Committee by means of warnings and undertakings during that year, and
(iii) the reasons why the allegations referred to in sub-paragraph (ii) were not referred to the Statutory Committee.

1.2 The ongoing pandemic has presented challenges to the work of the Committee as meetings have continued online. Managing such meetings remotely has been difficult and I would like to record the Committee's appreciation of the extraordinary efforts of Pharmaceutical Society NI staff and the understanding of all those involved in the fitness to practise processes to ensure the continued effectiveness, fairness and transparency of the Committee's work during this past year.

2 Composition of the Scrutiny Committee

The Scrutiny Committee, which sat during 2021, consisted of a publicly recruited panel, trained in fitness to practise proceedings.

Following her appointment as a NI Coroner, the Deputy Chair and legally qualified member, Ms Louisa Fee, resigned from the Committee on 16 September 2021. The legally qualified committee reserve member, Mr Paddy McDaid, was appointed by the Council of the Pharmaceutical Society NI as the new Deputy Chair.

On behalf of the Committee, I want to thank the Deputy Chair, Ms Louisa Fee, and wish her well in her new role.

Table 1: Table showing the membership of the Scrutiny Committee in 2021	
Chair and legally qualified member	Ms Nicole Lappin
Deputy Chair and legally qualified member (resigned 16 September 2021)	Ms Louisa Fee
Deputy Chair and legally qualified member (from 16 September 2021)	Mr Paddy McDaid**
Lay member	Mr Andrew Popplewell
Lay member	Mr Colin Kennedy
Pharmacist member	Ms Rachel Lloyd
Pharmacist member	Mr Andrew Dawson
Pharmacist member	Ms Anita Lawther
Pharmacist member	Ms Patricia Holden

** New Committee member.

3. Assignment of Scrutiny Committee panels in 2021

3.1 I assign members to panels on a rota basis unless the member is unavailable or where, for example, a potential conflict of interest exists in a particular case. Members from the Scrutiny Committee reserve list may also be utilised if a committee member is unavailable under Regulation 11(7) of the 2012 FtP Regulations. Under this regulation, I directed that a reserve lay member was co-opted for 3 connected cases which were scheduled when a lay committee member was not available to make a determination.

Table 2: Table showing the number of cases assigned to Scrutiny Committee members in 2021		
	Member	**Number of Panels**
Chair and legally qualified member	Ms Nicole Lappin	6
Deputy Chair and legally qualified member to (Resigned 16 September 2021)	Ms Louisa Fee	0
Deputy Chair and legally qualified member to (From 16 September 2021)	Mr Paddy McDaid**	1

Lay member	Mr Andrew Popplewell	2
Lay member	Mr Colin Kennedy	2
Reserve Lay Member	Mr Paul Corrigan	3
Pharmacist member	Ms Rachel Lloyd	1
Pharmacist member	Mr Andrew Dawson	2
Pharmacist member	Ms Anita Lawther	1
Pharmacist member	Ms Patricia Holden	3

4. Background

4.1 Following the enactment of new legislation in October 2012, additional powers enable the Fitness to Practise Committees of the Pharmaceutical Society NI to take more proportionate approaches to the management of fitness to practise case outcomes than simply removal from the Register.

The Committees are empowered to:

- give advice;
- issue formal warnings;
- agree undertakings;
- place conditions on the practise of a pharmacist;
- impose suspension;
- issue interim orders; and
- remove Registrants from the Register.

4.2 Fitness to Practise Committees

Under the legislation, two Committees have been established which determine allegations regarding fitness to practise.

4.2.1 Scrutiny Committee (Initial Proceedings)

This Committee considers initial allegations on a paper-based format and it has the power to dismiss a case, give advice, issue warnings and agree undertakings, if appropriate, and refer more serious cases to the Statutory Committee (subject to threshold criteria).

4.2.2 Statutory Committee (Hearings Committee)

This Committee considers allegations at hearings of misconduct of registered pharmacists. Registrants are invited to make representations with legal support should they so wish. The Statutory Committee deals with all categories of alleged impairment referred to it by either the Registrar or the Scrutiny Committee and may utilise the full range of fitness to practise sanctions i.e., give advice, issue formal

warnings, agree undertakings, place conditions on the practice of a pharmacist, impose suspension and remove registrants from the Register. It also deals with interim orders, restoration applications and review hearings.

5. The Work of the Scrutiny Committee in 2021

The Committee sat on seven occasions during the reporting period, dealing with a total of seven cases.

A table outlining the date of the meeting, the Registrar's recommendation in each case and the method of disposal by the Committee is shown below at Table 3.

All cases were examined using the published Pharmaceutical Society NI 2020 Threshold Criteria. These criteria guide the Scrutiny Committee as to how to assess which cases meet the criteria for referral to the Statutory Committee. Following the Committee's deliberation, I provide a full written determination setting out how these criteria have been applied in each case.

The Scrutiny Committee must not refer any fitness to practise allegation to the Statutory Committee unless it is satisfied that there is a real prospect that the Statutory Committee will make a finding that the registered person's fitness to practise is impaired. In addition, the Scrutiny Committee must not refer any disqualification allegation to the Statutory Committee unless it is satisfied that there is a real prospect that the Statutory Committee will give a direction for disqualification.

The 'real prospect' test applies to both the factual allegations and to the question whether, if found proved, the facts could support a finding of impairment. Where there is doubt as to whether the real prospect test is met, case law indicates that the Scrutiny Committee should err in favour of referral to the Statutory Committee.

The Scrutiny Committee concluded that in five of the seven cases before it, (Registrants A, B, C, D, and G), the threshold for referral to the Statutory Committee was met and these cases are not discussed further in this report.

The Scrutiny Committee dealt with the remaining two cases (Registrants E and F), using the powers granted to it by the legislation. In respect of Registrant E, the Committee was not satisfied that there was a real prospect that the Statutory Committee would make a finding that the registered person's fitness to practise is impaired and, following consideration of the evidence and the options available to it, disposed of case by way of advice to the Registrant.

In respect of Registrant F, the Committee was not satisfied that there was a real prospect that the Statutory Committee would make a finding that the registered

person's fitness to practise is impaired and, following consideration of the evidence and the options available to it, disposed of case by way of a warning to the Registrant. Further information on this case is provided in Section 7 of this report which deals with Regulation 7(1)a(iii).

Table 3:	**Table showing the recommendation of the Registrar compared to the method of disposal by the Scrutiny Committee.**		
Registrant	**Date of meeting**	**Registrar's recommendation for disposal**	**Disposal by the Scrutiny Committee**
A	16/3/21 28/5/21 then 24/6/21	Referral to Statutory Committee	Referral to Statutory Committee
B	16/3/21 28/5/21 then 24/6/21	Referral to Statutory Committee	Referral to Statutory Committee
C	19/4/21	Advice	Referral to Statutory Committee
D	10/12/21	Referral to Statutory Committee	Referral to Statutory Committee
E	10/12/21	Referral to Statutory Committee	Advice
F	10/12/21 then 17/12/21	Referral to Statutory Committee	Warning
G	15/12/21	Referral to Statutory Committee	Referral to Statutory Committee

6. The statutory purpose of this report

6.1 Regulation 7(1) a(i): “Trends, Patterns and Learning Points”.

As required by legislation, the key purpose of this report is to identify “trends, patterns and learning points” and bring these to the attention of the Council of the Society with a view to enabling issues to be identified at as early a stage as possible.

6.1.1 Trends and Patterns

Of the seven cases dealt with by the Scrutiny Committee during the reporting period, five met the statutory criteria and were referred to the Statutory Committee. In the remaining two cases, which related to the same incident, unlicensed medicines were manufactured without accompanying manufacturing records having been completed and retained. In relation to Registrant E, the Committee concluded that advice should be issued, and, in the second case, the Committee concluded that Registrant F should be issued with a warning.

The cases which come before the Committee highlight a diverse mix of cases but, given the low numbers of cases again this year, it was impossible to discern any pattern of concern.

6.1.2 Learning Points

Each panel considering a case comprises of a legal Chair, a Lay member and a pharmacist member. The Pharmacist members were asked to comment on any learning points which had arisen in each case they were involved in, as they are best placed to comment on what may or may not be the considered view of the average member of the profession. Other members were asked to put forward any points they felt may be relevant from their more general experience.

Below is a summary of the points made by Committee members as to what could be considered learning points which were considered and gathered from the panel members at the end of each meeting on the dates given. These are issues which may already be addressed in training and guidance given to the profession but, as they have arisen in the context of the Committee’s caseload, these may be areas where further emphasis may be needed. That would be a matter for the Pharmaceutical Society NI to consider.

Learning points for the profession – recorded at the Scrutiny Committee meetings in 2021.

Meeting dates 10-12-2021 and 17-12-2021

Extemporaneously prepared unlicensed medicine

(i) In relation to extemporaneously prepared unlicensed medicine, Registrants must ensure that any manufacturing records are completed and retained in accordance with Section 4 of the Pharmaceutical Society of Northern Ireland's Professional Standards and Guidance for the Sale and Supply of Medicines.

(ii) Registrants must ensure that all extemporaneously prepared unlicensed medicines are accurately labelled in accordance with Section 4 of the Pharmaceutical Society of Northern Ireland's Professional Standards and Guidance for the Sale and Supply of Medicines.

Meeting date 17-12-22

Responsible Pharmacist

(iii) When completing a Responsible Pharmacist Course and on appointment, Registrants should reflect on their duties and responsibilities as a Responsible Pharmacist and how those relate to the actions of others within the pharmacy while they perform that role.

(iv) When reflecting on the Responsible Pharmacist's duties and responsibilities, Registrants should consider the need for good governance and proper auditing trails and how these are implemented in practice in relation to all aspects of their professional duties.

Candour

(v) Registrants should reflect on their responsibility under the duty of candour to raise concerns about the practice of colleagues when that practice breaches the Pharmaceutical Society of Northern Ireland Professional Standards and Guidance for the Sale and Supply of Medicines or where their conduct contravenes any other provision regarding professional practice. Further, they should identify the steps they should take when such conduct comes to their attention. This includes identifying to whom such conduct must be reported.

Inspections or Audits

(vi) In relation to any inspections or audits carried out in respect of the Registrant's working practices, it is imperative that Registrants ensure that all issues identified in the course of such inspection or audit are addressed and acted on in full and in a timely manner.

Standard Operating Procedures

(vii) It is imperative that Registrants ensure that they are cognisant of all Standard Operating Procedures and that they follow them while performing their duties.

Training

(viii) It is imperative that Registrants ensure they apply the learning from training received in relation to their professional practice.

7. Regulation 7(1)a(ii): "Details of disposals by warnings and undertakings"

As required by the legislation mentioned earlier, the second purpose of this report is to identify those cases where the Scrutiny Committee was able to dispose of the case by way of warnings and/or undertakings rather than refer the case on to the Statutory Committee.

Under Regulation 7(1)a(iii) of FtP Regulations 2012: Reasons for non-referral to Statutory Committee, the Scrutiny Committee must not refer any fitness to practise allegation to the Statutory Committee, unless it is satisfied that there is a real prospect that the Statutory Committee will make a finding that the registered person's fitness to practise is impaired (Regulation 10(8)(a) of FtP Regulations 2012).

One case was disposed of by a warning (Registrant F) during the reporting period.

In this case, it was alleged that as a Responsible Pharmacist, the registrant had:

a) extemporaneously prepared unlicensed medicine (namely teething powders) in a community pharmacy with an incorrect manufacturing date on the manufacturing record and labels, contrary to the Pharmaceutical Society of Northern Ireland's Professional Standards and Guidance for the Sale and Supply of Medicines (Section 4);

b) extemporaneously prepared unlicensed medicine (namely teething powders) in a community pharmacy with inadequate manufacturing records (lacking

manufacturer details, batch numbers, expiry dates and a note of who prepared the teething powders) contrary to the Pharmaceutical Society of Northern Ireland's Professional Standards and Guidance for the Sale and Supply of Medicines (Section 4);

c) labelled and offered for sale in a community pharmacy an extemporaneously prepared unlicensed medicine (namely teething powders) with an incorrect manufacturing date and incorrect expiry date contrary to the Pharmaceutical Society of Northern Ireland's Professional Standards and Guidance for the Sale and Supply of Medicines (Section 4);

d) the registrant extemporaneously prepared unlicensed medicine (namely colic mixture) in in a community pharmacy with inadequate manufacturing records (lacking manufacturer details, batch numbers and expiry dates) contrary to the Pharmaceutical Society of Northern Ireland's Professional Standards and Guidance for the Sale and Supply of Medicines (Section 4);

e) labelled and offered for sale in a community pharmacy extemporaneously prepared unlicensed medicines (namely teething powders and colic mixture) with approximate and imprecise expiry dates contrary to the Pharmaceutical Society of Northern Ireland's Professional Standards and Guidance for the Sale and Supply of Medicines (Section 4); and

f) failed to ensure that the extemporaneous preparation of unlicensed medicines at a community pharmacy complied with the Pharmaceutical Society of Northern Ireland's Professional Standards and Guidance for the Sale and Supply of Medicines (Section 4) and adequately protected the public.

It was submitted on behalf of the Pharmaceutical Society that the relevant threshold criterion in this case were as follows:

Criterion (a) – The pharmacist's conduct, ethics or performance presents an actual or potential risk to patient or public safety.

Criterion (b) – The pharmacist's conduct, ethics or performance undermines, or is likely to undermine, confidence in the pharmacy profession.

Criterion (c) – The pharmacist's conduct, ethics or performance reveals a serious or persistent failure to meet the standards for pharmacists laid down in the Code.

Following consideration of the evidence, the Scrutiny Committee concluded that the Registrant accepted that they contravened the Pharmaceutical Society of Northern Ireland's Professional Standards and Guidance for the Sale and Supply of Medicines

(Section 4) in relation to keeping accurate records and ensuring accurate labelling of manufactured medicines. The Committee concluded further that the Registrant accepted they were the Responsible Pharmacist and acknowledged that recording the incorrect manufacturing date on the manufacturing record and labels was an oversight on their part.

The Registrant further accepted that they were the Responsible Pharmacist when a batch of medicine was manufactured and accepted that the details on the manufacturing record should have been fully recorded on each occasion when the medicine was manufactured.

Further, the Committee also noted the Registrant accepted that, while being the Responsible Pharmacist, labels on the medicine contained an incorrect manufacturing date and incorrect expiry date and, in addition, when a batch of a different medicine was manufactured, they accepted that the manufacturing record should have included the manufacturer details, batch numbers, and expiry dates.

The Committee was disappointed that, in relation to three dates, the Registrant accepted failings in relation to accurate record keeping and the appropriate labelling of unlicensed medicine. This followed the Registrant signing documents which related to these two activities. On one document, namely the Standard Operating Procedure, they had been reminded to complete the manufacturer, batch number and expiry date when completing the extemporaneous preparation sheet. The worksheets had pre-populated headings e.g., manufacturer, batch number and expiry date, to prompt pharmacists to complete these, yet the Registrant accepted they had failed to do so.

The Committee also noted that the Registrant signed a staff training record where they had acknowledged that they had been trained in the equipment, method of preparation, labelling and record keeping to meet recognised standards in relation to the preparation of the medicines involved and it is, therefore, concerning in relation to patient safety and in ensuring public confidence in the profession that the Registrant accepts they failed to keep accurate records following receipt of this training.

In accordance with paragraph 6(1) of Schedule 3 to the 1976 Order, the Scrutiny Committee considered whether the allegation ought to be considered by the Statutory Committee. The Scrutiny Committee must not refer any fitness to practise allegation to the Statutory Committee unless it is satisfied that there is a real prospect that the Statutory Committee will make a finding that the registered person's fitness to practise is impaired (Regulation 10(8)(a) of FtP Regulations 2012).

Having considered all the evidence in relation to Registrant F, the decision of the Scrutiny Committee was that, given the facts of the matter, it was not satisfied that there was a real prospect of such a finding by the Statutory Committee. The

Committee then considered, in ascending order, the various methods of disposal available to it and determined that the appropriate method of disposal was to issue a warning to the Registrant in order to safeguard public safety and maintain public confidence.

Accordingly, the decision of the Scrutiny Committee was that the following warning should be issued to the Registrant.

I. In relation to extemporaneously prepared unlicensed medicine, it is imperative that the Registrant ensures that any manufacturing records are completed in full and retained in accordance with Section 4 of the Pharmaceutical Society of Northern Ireland's Professional Standards and Guidance for the Sale and Supply of Medicines.

II. In relation to extemporaneously prepared unlicensed medicine, it is imperative that the Registrant ensures these are accurately labelled in accordance with Section 4 of the Pharmaceutical Society of Northern Ireland's Professional Standards and Guidance for the Sale and Supply of Medicines.

III. In relation to all aspects of record keeping, it is imperative that the Registrant ensures that they maintain accurate records at all times in accordance with Section 4 of the Pharmaceutical Society of Northern Ireland's Professional Standards and Guidance for the Sale and Supply of Medicines.

IV. In relation to any inspections or audits carried out in respect of the Registrant's working practices, it is imperative that the Registrant ensures that all issues identified in the course of such inspection or audit are addressed and acted on in full in a timely manner.

V. In relation to their professional practice, it is imperative that the Registrant ensures that the Registrant is cognisant of all Standard Operating Procedures and follows them while performing their duties.

VI. In relation to their professional practice, it is imperative that the Registrant ensures that they apply the learning from training received.

8. Conclusion

As Scrutiny Committee Chair, I believe that Committee members have found the work they have been tasked with to be challenging, varied and interesting.

I want to express the Committee's appreciation of the support by Pharmaceutical Society staff to the Committee to enable it to fulfil their role. In particular, I would like

to thank Simon McClenahan, the Scrutiny Committee Secretary, for his assistance in the preparation of this report. I look forward to working further with him and others as the Committee carries out its role to protect the safety of patients and maintain the reputation of the profession.

I trust that this report will again provide a useful insight into the work of the Scrutiny Committee in the past year and reassurance to the Society that these important issues are being addressed in accordance with the legislation in a satisfactory and proportionate way.

Accordingly, I commend this report to you.

Nicole Lappin
Chair
Scrutiny Committee of the Pharmaceutical Society NI

28 February 2022